

information. However, the non-patent reference listed on page 1 of the Form PTO-1449 was not initialed to acknowledge consideration of this reference. Thus, the Examiner is requested to initial and return to the undersigned a copy of the subject Form PTO-1449 acknowledging this reference as well. For the convenience of the Examiner, copies of the initial form and the partially initialed version thereof are attached hereto.

Applicant appreciates the courtesies extended to his representative during the February 11, 2003 personal interview. During the interview, the Examiner was specifically invited to contact Applicant's representative if any questions arise during further examination or if any amendment could be made to expedite allowance. Applicant's separate record of the substance of the interview is incorporated into the following remarks.

Applicant also appreciates the indication that claim 89 is allowable. The other pending claims are allowable for at least the reasons discussed below. Thus, it is respectfully submitted that the entire application is in condition for allowance.

Claims 21-34, 36-53, 56-60, 63-88, 90-94, 109-112 and 121-124 are rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-37, 48-83 and 87-89 of U.S. Patent No. 6,238,368. A Terminal Disclaimer over the applied patent is attached hereto. Based on the filing of this Terminal Disclaimer, it is respectfully submitted that the obviousness-type double patenting rejection should be withdrawn.

Claims 21-35, 41-46, 48-71, 77-83 and 90-124 are rejected under 35 U.S.C. §103 over Zilber in view of Kunz et al. Applicant respectfully traverses the rejection.

Zilber is directed to a urethral stent. As noted in the Office Action, Zilber fails to disclose a cytoreductive agent positioned along the stent described therein. In addition, Kunz does not overcome the deficiencies of Zilber.

As noted in the Office Action, Kunz is directed to methods for inhibiting stenosis following vascular trauma or disease in a mammalian host. The method comprises administering a therapeutically effective dosage of a therapeutic conjugate containing a

vascular smooth muscle binding protein, which associates in a specific manner with a cell surface of the vascular smooth muscle cell, coupled to a therapeutic agent that inhibits a cellular activity of the muscle cell. See the Abstract. To administer this therapeutic conjugate, Kunz specifically teaches utilizing an infusion catheter. Kunz also teaches that the therapeutic conjugate can be administered by intravenous, intralymphatic, intrathecal, intraarterial, local delivery by implanted osmotic pumps or other intracavity routes. Col. 30, line 66 – col. 31, line 28. Although Kunz specifically describes using the therapeutic conjugate described therein for treating vascular trauma caused by a stent, Kunz does not teach or suggest positioning the therapeutic conjugate taught therein along the stent. Col. 10, lines 38-44. In addition, although Kunz teaches dispersing the therapeutic agent within a non-biodegradable or biodegradable-polymeric structure, Kunz does not teach or suggest that this non-biodegradable structure forms part of a stent. Col. 24, lines 46-49. Thus, Kunz does not overcome the deficiencies of Zilber.

In addition, Zilber cannot properly be combined with Kunz. In particular, Zilber is directed to a urethral stent. In contrast, Kunz is directed to methods and agents for treating vascular smooth muscle cells. There would have been no motivation to combine the urethral stent described in Zilber with the vascular therapeutic agents described in Kunz to achieve the present invention. In particular, there would clearly be no motivation to combine the teaching of Kunz of method and agents for treating vascular smooth muscle cells with the stent of Zilber to achieve the invention of claim 21 and the claims dependent thereon, as well as claims 106, 108, 110, 112, 114, 116, 118, 120, 122, 124 and new claim 126, which are directed to therapeutic devices or methods for treating a prostatic portion of male urethra.

Zilber cannot properly be combined with Kunz in order to achieve the present invention. In addition, even if improperly combined, Kunz does not overcome the deficiencies of Zilber. Therefore, the rejection of claims 21-35, 41-46, 48-71, 77-83 and 90-124 over these references should be reconsidered and withdrawn.

Claims 38 and 74 are rejected under 35 U.S.C. §103 over Zilber in view of Kunz, and further in view of Silvestrini. Applicant respectfully traverses the rejection.

Zilber and Kunz fail to teach or suggest the present invention for at least the reasons discussed above. In addition, Silvestrini is cited for the teaching of a hydrophilic and expandable substrate, as recited in claims 38 and 74. However, Silvestrini does not teach or suggest the features of the base claims on which claims 38 and 74 depend. Therefore, the rejection of claims 38 and 74 in view of Zilber, Kunz and Silvestrini should be reconsidered and withdrawn.

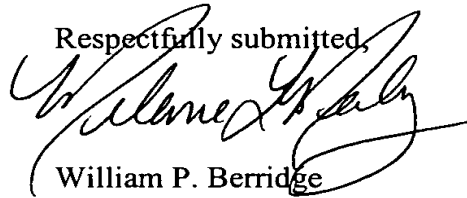
Claims 36, 37, 39, 40, 72, 73, 75 and 76 are rejected under 35 U.S.C. §103 over Zilber in view of Kunz, and further in view of Yamamoto et al. Applicant respectfully traverses the rejection.

Zilber and Kunz fail to teach or suggest the present invention for at least the reasons discussed above. In addition, Yamamoto does not overcome the deficiencies of Zilber and Kunz. In particular, Yamamoto do not teach or suggest all of the features of the base claims on which claims 36, 37, 39, 40, 72, 73, 75 and 76 depend. Therefore, the rejection of these claims over Zilber, Kunz and Yamamoto should be reconsidered and withdrawn.

Claims 125-128 have been added to further define the invention. Claim 125 is directed to a therapeutic device intended for being substantially fully located in a natural lumen through which a fluid naturally flows, comprising a non-biodegradable active tubular element that is designed to be placed in at least an obstructed part of the natural lumen, upstream of a sphincter, wherein the element comprises a therapeutic agent that causes reduction of the obstruction supported by and arranged around and along said active element. Claims 126-128 depend from claim 125. The cited references do not teach or suggest the invention of these claims for at least the reasons discussed above.

In view of the above amendments and remarks, it is respectfully submitted that the present application is in condition for allowance. Favorable consideration and prompt allowance are therefore respectfully requested.

Should the Examiner believe that anything further would be desirable in order to place this application in better condition for allowance, the Examiner is invited to contact Applicant's undersigned representative at the telephone number set forth below.

Respectfully submitted,  
  
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WPB:MLM/jam

Attachments:

Appendix  
Form PTO-1449 (originally filed and partially initialed copies)  
Terminal Disclaimer

Date: February 11, 2003

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<p>DEPOSIT ACCOUNT USE AUTHORIZATION Please grant any extension necessary for entry; Charge any fee due to our Deposit Account No. 15-0461</p>
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## APPENDIX

### Changes to Claims:

Claims 125-128 are added.

The following is a marked-up version of the amended claims:

36. (Amended) The device of claim 34, wherein said ~~eytoreductive-agent~~substrate and said internal core are off-centered in relation to one another.

39. (Amended) The device of claim 34, further comprising a sheath made of a synthetic foam between said ~~eytoreductive-agent~~substrate and said internal core.